



News Flash - The *Clinical Laboratory Fee Schedule Fact Sheet*, which provides general information about the Clinical Laboratory Fee Schedule, coverage of clinical laboratory services, and how payment rates are set, is now available in downloadable format from the Centers for Medicare & Medicaid Services Medicare Learning Network at http://www.cms.hhs.gov/MLNProducts/downloads/clinical_lab_fee_schedule_fact_sheet.pdf on the CMS website. The *Clinical Laboratory Fee Schedule Fact Sheet*, is also available in print format. To place your order, visit <http://www.cms.hhs.gov/mlngeninfo/>, scroll down to "Related Links Inside CMS" and select "MLN Product Ordering Page."

MLN Matters Number: MM6060

Related Change Request (CR) #: 6060

Related CR Release Date: June 20, 2008

Effective Date: July 1, 2008

Related CR Transmittal #: R1538CP

Implementation Date: July 7, 2008

New Waived Tests

Provider Types Affected

Providers and suppliers submitting claims to Medicare contractors (carriers and/or Part A/B Medicare Administrative Contractors (A/B MACs)) for clinical laboratory services provided to Medicare beneficiaries.

Provider Action Needed



STOP – Impact to You

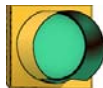
This article is based on Change Request (CR) 6060 which informs Medicare contractors of new waived tests approved by the Food and Drug Administration (FDA) under Clinical Laboratory Improvement Amendments of 1988 (CLIA).

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**CAUTION – What You Need to Know**

These 24 newly added CLIA waived tests are marketed immediately after approval and, through CR6060, the Centers for Medicare & Medicaid Services (CMS) notifies its Medicare contractors of the new tests so that the contractors can accurately process claims.

**GO – What You Need to Do**

See the Background and Additional Information Sections of this article for further details regarding these changes.

Background

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that the CMS only pay for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

The following table includes the latest new tests approved by the Food and Drug Administration as waived tests under CLIA. The Current Procedural Terminology (CPT) codes for these new tests must have the modifier QW to be recognized as a waived test.

CPT Code	Effective Date	Description
86318QW	February 1, 2005	Alfa Scientific Designs Instant View H. Pylori Whole Blood Rapid Test
82977QW, 84460QW	January 22, 2007	Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 6 Panel){Whole Blood}
82977QW, 84460QW	January 22, 2007	Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 6 Panel){Whole Blood}
82150QW, 82977QW, 84075QW, 84460QW	January 22, 2007	Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood}
82150QW, 82977QW, 84075QW, 84460QW	January 22, 2007	Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood}
82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84450QW, 84520QW	March 14, 2007	Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 6 Panel){Whole Blood}
82565QW, 82947QW, 82950QW, 82951QW,	March 14, 2007	Abaxis Piccolo xpress Chemistry Analyzer

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CPT Code	Effective Date	Description
82952QW, 84450QW, 84520QW		(General Chemistry 6 Panel){Whole Blood}
82042QW, 82247QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84157QW, 84450QW, 84520QW, 84550QW,	March 14, 2007	Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood}
82042QW, 82247QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84157QW, 84450QW, 84520QW, 84550QW,	March 14, 2007	Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood}
80101QW	June 28, 2007	Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Test
80101QW	June 28, 2007	Alfa Scientific Designs, Inc. Instant-View Multi-Drug of Abuse Urine Cup Test
82330QW, 82374QW, 82435QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 84520QW	September 21, 2007	Abbott i-STAT Chem8+ Cartridge {Whole Blood}
82274QW, G0328QW	October 5, 2007	BTNX Inc. Rapid Response Fecal Occult Blood (FOB) Self Test
82274QW, G0328QW	October 5, 2007	BTNX Inc. Know Fecal Occult Blood (FOB) Self Test
80101QW	January 8, 2008	Abbott Diagnostics Signify ER Drug Screen Test
86308QW	January 8, 2008	Jant Pharmacal Accutest Value + Mononucleosis Rapid Test {Whole Blood}
86308QW	January 8, 2008	Stanbio Rely Mono Rapid Test{Whole Blood}
87880QW	January 22, 2008	Becton Dickinson BD Chek Group A Strep A Test

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CPT Code	Effective Date	Description
86318QW	January 22, 2008	Diagnostic Test Group Clarity H. pylori Rapid Test Device {Whole Blood}
80101QW	January 30, 2008	BTNX Inc. Rapid Response Multi-Drug One Step Screen Test Panel (Urine)
80101QW	January 30, 2008	BTNX Inc. Know Multi-Drug One Step Screen Test Panel (Urine)
87807QW	February 25, 2008	Quidel Quick Vue RSV Test
84443QW	February 29, 2008	Qualigen, Inc. FastChek TSH {Whole Blood}
83036QW	March 31, 2008	Bayer A1CNow+ {For professional use}

The new waived CPT/Healthcare Common Procedure Coding System (HCPCS) code(s),

- 84550QW has been assigned for the uric acid test performed using the Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood} and the Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood}; and
- 82330QW, 82374QW, 82435QW, 84132QW and 84295QW have been assigned for the ionized calcium, carbon dioxide, chloride, potassium, and sodium tests performed using the Abbott i-STAT Chem8+ Cartridge {Whole Blood}.

Previously, CR 5913 (see

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5913.pdf> on the CMS website) assigned the following CPT/HCPCS codes:

- 80048QW for the tests performed using the Abaxis Piccolo Blood Chemistry Analyzer (Basic Metabolic Reagent Disc){Whole Blood} and the Abaxis Piccolo xpress Chemistry Analyzer (Basic Metabolic Reagent Disc){Whole Blood}; and
- 80053QW for the tests performed using the Abaxis Piccolo Blood Chemistry Analyzer (Comprehensive Metabolic Reagent Disc){Whole Blood} and the Abaxis Piccolo xpress Chemistry Analyzer (Comprehensive Metabolic Reagent Disc){Whole Blood}.

The effective date for the above CPT/HCPCS codes mentioned in CR 5913 is revised from January 16, 2008 to October 30, 2007.

CR 6060 also includes an attachment listing tests granted waived status under CLIA. The tests mentioned on the first page of the attachment (i.e., CPT codes: 81002, 81025, 82270, 82272, G0394, 82962, 83026, 84830, 85013, and 85651) do not require a QW modifier to be recognized as a waived test.

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Additional Information

The official instruction, CR 6060, issued to your carrier and A/B MAC regarding this change may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R1538CP.pdf> on the CMS website.

If you have any questions, please contact your carrier or A/B MAC at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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